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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/603,279 | 06/25/2003 | Lee Michael Teras | 9286 | 4437 |

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THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
WINTON HILL TECHNICAL CENTER - BOX 161
6110 CENTER HILL AVENUE
CINCINNATI, OH 45224

[REDACTED] EXAMINER

HENDRICKS, KEITH D

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1761

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/603,279 | TERAS ET AL. | |

| | | |
|-----------------|-----------------|--|
| Examiner | Art Unit | |
| Keith Hendricks | 1761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-44 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 25 June 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3-17-04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: ____ . |

DETAILED ACTION

Claim Rejections - 35 USC § 112

- i) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the addition of an “asparagine-reducing enzyme” (or, more accurately, asparaginase), does not reasonably provide enablement for any random method reaction of “reducing the level of asparagine in the corn-based food material.” The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

A number of factors must be considered in assessing the enablement of an invention, including the following: the breadth of the claims, the amount of experimentation necessary, the guidance provided in the specification, working examples provided, predictability, and the state of the art. See *In re Wands*, 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Circ. 1988). The limited specific guidance and examples provided in the specification demonstrate the addition of asparaginase to corn foodstuff material. No other means by which the level of asparagine (and thus upon heating, acrylamide) are provided. The breadth of the claims is such that it encompasses numerous means by which one skilled in the art may reduce the level of asparagine, yet the specification does not provide the skilled artisan with such knowledge and guidance. Thus, apart from the single exemplified method, one skilled in the art is left to their own means of random experimentation in order to determine a method best suited for “reducing the level of asparagine.” Therefore, the specification in light of claim 6 does not reasonably provide sufficient enablement a person skilled in the art to perform the broadly-claimed invention.

- ii) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-5, 7-10, 11-30 and 41-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "reduced", in product claims 11-30 and 41-44, is a relative term which renders the claim indefinite. The term "reduced" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "reduced" indicates both a current condition and a previous condition, as well as a change from the previous to the current state. A product, as it stands in its current state, cannot simply be "reduced", without reference to a standard or to the previous condition. Further, as an example, if two distinct food products each contain 350 ppb of acrylamide, where one naturally contained said amount and one had been processed according to the invention, given this data alone, it would be impossible for one skilled in the art to determine which one had been "reduced" from a previously higher amount, and which one was naturally at this level. Still further, it is noted that a food product cannot have a "reduced amount of acrylamide", if it never had a previous level of acrylamide, as is the case with corn-based food products which have not yet been heated to form acrylamide.

The term "asparagine-reducing enzyme" in claims 1-5 and 7-10 may be misleading, as this is not an actual oxido-reductase class of enzyme (Enzyme Classification # 1.____). Rather, asparaginase belongs to the hydrolase class of enzymes (E.C. # 3.5.1.1). Thus, it does not actually perform a typical (oxido)reduction reaction, within the means of describing enzymes and their activities. While applicant presumably intends this term to broadly encompass any enzyme which reduces the amount of asparagine in the product, it is technically improper. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). Thus this term is indefinite as used in the instant claims.

In part (1) of claim 5, the method generally recites "a food material", but does not indicate that the material is a corn-based food material, as stated in the preamble. A preamble is generally not accorded patentable weight where it merely recites the purpose of a process or the intended use of a

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structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In this case, the process steps stand alone, and thus it is unclear if the claimed method is actually limited to a corn-based food material. See claim 10, in contrast.

The term "low" in (at least) claims 42 and 44, is a relative term which renders the claims indefinite. The term "low" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is no standard or original amount of acrylamide provided in the specification such that one skilled in the art (or a consumer of the claimed article) would be apprised of what constituted a "low" amount of acrylamide within the article.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4~~4~~ are rejected under 35 U.S.C. 103(a) as being unpatentable over Elder et al. (Pub. No. US 2004/0058054).

Elder et al. discloses "a method for reducing the amount of acrylamide in thermally processed foods" (abstract). At paragraph 0004, it is stated that "acrylamide has especially been found in carbohydrate food products that have been processed at high temperatures. Examples of foods that have tested positive for acrylamide include coffee, cereals, cookies, potato chips, crackers, french-fried potatoes, breads and rolls, and fried breaded meats." Paragraph 0008 states that "an example of a thermally processed food ingredient is potato flakes, which is formed from raw potatoes in a process that exposes the potato to temperatures as high as 200.degree. C. Examples of other thermally processed food ingredients include processed oats, par-boiled and dried rice, cooked soy products, corn masa, roasted

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coffee beans and roasted cacao beans.” A “significant formation of acrylamide has been found to occur when the amino acid asparagine is heated in the presence of a simple sugar” (par. 0009). “One such method for inactivating is to contact asparagine with the enzyme asparaginase. This enzyme decomposes asparagine to aspartic acid and ammonia” (par. 0011). This reaction was performed in Example 5, where it is demonstrated that such treatment “with an enzyme that decomposes asparagine to aspartic acid and ammonia reduced acrylamide formation by more than 99.9%. This experiment establishes that reducing the concentration of asparagine, or the reactive nature or [‘of’; sic] asparagine, will reduce acrylamide formation.”

Thus, given the direct teaching and guidance provided by the reference, it would have been obvious to one of ordinary skill in the art to have added an asparaginase enzyme to corn-based food products or a corn-based food ingredient prior to heating/cooking, in order to reduce the level of asparagine within the product, and ultimately to prevent the formation of high levels of acrylamide within the final food product. The reference specifically disclosed various processed food products which were known to contain high levels of acrylamide, and also disclosed a specific effective means to solve this problem. The reference also effectively demonstrated the activity of the enzyme in a food system, as shown in Example 5. Thus, the claimed invention is considered obvious in light of the teachings of the reference, and the state of the art at the time the invention was made. Regarding the specific amounts and percentage levels of asparagine and acrylamide in the resultant products of the instant claims, this would have been an inherent result of the natural function of the enzyme and method disclosed, as shown by the fact that Example 5 “reduced acrylamide formation by more than 99.9%.” This would have been expected to function similarly across multiple food products, including corn chips, flakes and tortillas, each of which contain free asparagine which would otherwise have been converted to acrylamide in the heating process.

Regarding claims 41-44, it would have been obvious to one of ordinary skill in the art to have packaged and appropriately labeled the food products produced by Elder et al. Packaging and labeling techniques were well-known and common in the art, especially regarding any potential special feature that might draw the interest of the consumer. Regarding the particular message, it is noted that the printed word itself would not significantly change the claimed article of matter, and would not provide a patentable distinction, *per se*, over the known prior art package materials and methods. It is recognized, however, that if eventually the instant product claims directed to the food materials with “reduced levels of asparagine [or acrylamide]” were to be found allowable over the prior art, then the article container claims 41-44 would also be allowable, if reasonably commensurate in scope.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

i) Claims 41-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-12 of copending Application No. 10/606,260. Although the conflicting claims are not identical, they are not patentably distinct from each other because they each are directed to an article of commerce comprising (a) a snack chips food product with a reduced level of acrylamide; (b) a container for containing the product, and (c) a message associated with the container, wherein said message associated with the container informs the consumer that the product has a "reduced level of acrylamide."

ii) Claims 1-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 and 42-50 of copending Application No. 10/606,137. Although the conflicting claims are not identical, they are not patentably distinct from each other because they each are directed to food products with reduced amounts of asparagine and/or acrylamide; methods of making said products; and articles of commerce comprising said products (as explained above with regard to copending application 10/606,260).

iii) Claims 11-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/603,978. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to corn-based food materials and articles of commerce with "reduced level

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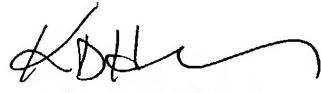
of acrylamide", as produced by any method, and the copending claims are directed to methods of producing food materials with reduced levels of acrylamide, as well as articles of commerce containing such (as explained above with regard to copending application 10/606,260).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (571) 272-1401. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



KEITH HENDRICKS
PRIMARY EXAMINER